

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-127

MICROBIOLOGY REVIEW

REVIEW FOR HFD-550
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #1 of NDA 21-127
17 September 1999

SEP 17 1993

- APPLICANT: Asta Medica
890 East Street
Tewksbury, MA 01876-1496

2. **PRODUCT NAMES:** Azelastine HCl Ophthalmic Solution, 0.05%
3. **DOSAGE FORM AND ROUTE OF ADMINISTRATION:**
The product is an ophthalmic solution for instillation into the eye.
4. **METHODS OF STERILIZATION:**
The product is filled using a process.
5. **PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:**
The product is indicated in the treatment of allergic conjunctivitis.

- B.
1. DATE OF INITIAL SUBMISSION: 2 August 1999
 2. DATE OF AMENDMENT: (none)
 3. RELATED DOCUMENTS: _____ NDA 20-114, DMF's

 4. ASSIGNED FOR REVIEW: 18 August 1999

- C. REMARKS: Product manufacturing, filling, and packaging will be performed by: _____

Gamma-irradiation sterilization of the container/closure system will be performed by:

~~_____~~
~~_____~~
~~_____~~
~~_____~~

D. CONCLUSIONS: The application is recommended for approval, pending the applicant's commitment to complete the studies indicated in "List of Microbiology Comments" post-approval.

~~/S/~~

Paul Stinavage, Ph.D.

17 September 1999

~~/S/~~

9/17/99

cc: Original NDA 21-127

HFD-550/Div. File/R. Rodriguez/L. Ng/R. Uppoor/W. Chambers

HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 17 September 1999

R/D initialed by P. Cooney

APPEARS THIS WAY
ON ORIGINAL

(b4)

9 page(s) have been removed because it contains trade secret and/or confidential information that is not disclosable.

REVIEW FOR HFD-550
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #2 of NDA 21-127
21 January 2000

JAN 24 2000

A. 1. NDA 21-127

APPLICANT: Asta Medica
890 East Street
Tewksbury, MA 01876-1496

2. PRODUCT NAMES: Azelastine HCl Ophthalmic Solution, 0.05%

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product is an ophthalmic solution for instillation into the eye.

4. METHODS OF STERILIZATION:
The product is filled using a _____ process.

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE
INDICATION:
The product is indicated in the treatment of allergic conjunctivitis.

B. 1. DATE OF INITIAL SUBMISSION: 2 August 1999

2. DATE OF AMENDMENT: 13 December 1999 (Subject of this
Review)

3. RELATED DOCUMENTS: _____ NDA 20-114, DMF's

4. ASSIGNED FOR REVIEW: 4 January 2000

C. REMARKS: Product manufacturing, filling, and packaging will be
performed by:

Gamma-irradiation sterilization of the container/closure system will be performed by:

D. CONCLUSIONS: The application is recommended for approval. This submission provides the commitment requested by the Microbiologist in Microbiologist's Review #1 of NDA 21-127 dated 17 September 1999. The applicant should be reminded to submit the results of the study when they are available.

/S/

Paul Stinavage, Ph.D.

21 January 2000

/S/ 1/24/00

cc: Original NDA 21-127
HFD-550/Div. File/M. Puglisi/L. Ng/R. Uppoor
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 21 January 2000
R/D initialed by P. Cooney

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